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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/243,342	05/16/94	BUCALA	R 731500B

EXAMINER	
TWOMEY, P	
ART UNIT	**PAPER NUMBER**
1804	14

DATE MAILED: 08/20/96

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NEW YORK, NY 10036-2711

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ~~three~~ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 63, 64, 80-93 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claims 63, 64, 80-93 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1996-409-290/40029

Part III DETAILED ACTION

Election/Restriction

1. Applicants amendment of June 25, 1996 is entered as Paper #13. Claims 65-79 are cancelled. Newly advanced claims 80-93 have been entered. In view of the new claims, further restriction is required.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 63, 64, 84-90, 92, and 93, drawn to methods of inhibiting MIF gene expression, classified in various classes and subclasses dependent upon the nature of the inhibitor, for example, methods employing antisense nucleic acids are classified in Class 514 subclass 44.

Claims 63, 64, 84-90, 92, and 93 are generic to a plurality of disclosed patentably distinct species comprising:

a. inhibiting MIF gene expression using antisense molecules

b. inhibiting MIF gene expression using ribozyme molecules

c. inhibiting MIF gene expression using triple helix-forming molecules

d. inhibiting MIF gene expression using steroids

The species delineated above are distinct, each from the other, because they utilize materially different biologic agents each of which requires separate areas of search and consideration. For example, species b requires search and consideration of nucleic acid molecules with catalytic enzyme

activity, whereas species d requires search and consideration of steroids.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Group II. Claim 91, drawn to therapy consisting of administering Agent A with Agent B, classified in various classes and subclasses dependent on the nature of the agent used, for example, methods employing antibodies are classed in Class 424, subclass 130.1.

Claim 91 is generic to a plurality of disclosed patentably distinct species comprising:

Agent A:

a. inhibiting MIF gene expression using antisense molecules

b. inhibiting MIF gene expression using ribozyme molecules

c. inhibiting MIF gene expression using triple helix-forming molecules

d. inhibiting MIF gene expression using steroids

The species delineated above are distinct, each from the other, because they utilize materially different biologic agents each of which requires separate areas of search and consideration. For example, species b requires search and consideration of nucleic acid molecules with catalytic enzyme activity, whereas species d requires search and consideration of steroids.

Agent B:

a. antibodies to TNF-α, IL-1, or IFN-γ

b. IL-1 receptor antagonist (IL-1RA)

c. IL-10

d. steroid or glucocorticoid

The species delineated as Agent B above are distinct, each from the other, because they utilize materially different biologic agents each of which requires separate areas of search and consideration. For example, species a requires search and

consideration of antibodies, whereas species d requires search and consideration of steroids.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Group III. Claim 80, drawn to a method of inhibiting MIF gene expression using antisense molecules, classified in Class 536, subclass 23.1.

Group IV. Claim 81, drawn to a method of inhibiting MIF gene expression using ribozyme molecules, classified in Class 536, subclass 23.1.

Group V. Claim 82, drawn to a method of inhibiting MIF gene expression using triple-helix forming molecules, classified in Class 536, subclass 24.5.

Group VI. Claim 83, drawn to a method of inhibiting MIF gene expression using steroids, classified in Class 540, subclass 24.

The inventions of groups III-VI are distinct, each from the other because they utilize materially different biologic agents each of which requires separate areas of search and consideration. For example, group III requires search and consideration of antisense molecules which act by binding to mRNA by Watson-Crick base pairing and physically blocking translation, whereas group IV requires search and consideration of triple-helix forming molecules which bind to DNA by non-Watson-Crick base pairing.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their divergent classifications and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

A telephone call was made to Jackie Benn on July 24, 1996 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Twomey, Ph.D. whose telephone number is (703) 305-7022. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached on (703) 308-3153. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patrick Twomey, Ph.D.

August 13, 1996

JACQUELINE M. STONE
SUPERVISORY PATENT EXAMINER
GROUP 1800